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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,478	09/15/2003	Rakesh Tuli	Q-75484	9837

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EXAMINER

JOIKE, MICHELE K

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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09/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/661,478

Applicant(s)

TULI ET AL.

Examiner

Michele K. Joike, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 21, 26, 29 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 26 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed June 20, 2007. Claims 1-19, 22-25, 27-28, 30-38 and 45-52 are canceled. Claims 20, 21, 26, 29 and 39-44 were amended.

Claims 20, 21, 26, 29 and 39-44 are pending, with claims 20, 21, 26 and 29 examined in the instant application. Applicants have requested rejoinder of method claims 39-44, however since the product claims are not in condition for allowance, the claims have not been rejoined.

Any rejection of record in the previous Office Action, mailed December 20, 2006, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Objections

Claims 39-44 are objected to because of the following informalities: These claims have the wrong status identifier. Claims 39-44 should be identified as amended and withdrawn. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1636

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 21, 26 and 29 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Arguments Concerning Claim Rejections – 35 USC § 112 (1)

Applicant's arguments and the Declaration under 37 CFR 1.132 filed June 20, 2007 have been fully considered but they are not found persuasive.

The following grounds of traversal are presented:

1. Table 1 discloses various domains cloned in multiple copies in front of the minimal promoter *P_{mec}*. The specification demonstrates that when domains are shuffled to place sequences in different locations, the resultant promoters activate transcription.

2. Applicants have submitted a Declaration under 37 CFR 1.132 filed June 20, 2007. The Declaration provides a detailed analysis of SEQ ID NO: 2 using saturation mutagenesis. Applicants studied the effect of 39 mutations on gene expression in plant cells. Double mutations were also made. Experiments revealed that several single mutations in the TATA-box region are tolerated *in vivo*. However, the majority of mutations resulted in a decrease or an increase of promoter expression as compared to the prototype promoter that contained the parent TATA sequence.

Art Unit: 1636

Applicant's arguments and the Declaration have not been found persuasive for the following reason.

1. As discussed in Applicant's arguments, Table 1 only discloses sequences added to the front of the minimal promoter, and does not disclose any variants of the minimal promoter. Therefore, Applicants have not demonstrated that variance of 25%-50% of the nucleotides would result in a promoter that can function similarly.

2. The declaration under 37 CFR 1.132 filed June 20, 2007 is insufficient to overcome the rejection of claims 20, 21, 26 and 29 based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph as set forth in the last Office action. Applicants only studied one domain, SEQ ID NO: 2. Mutation analysis performed on the other domains will not necessarily provide the same results. Furthermore, only single or double mutants were made and shown to be functional, so there is no evidence that a sequence with only 75% identity will still function to activate transcription. Also, as Applicants have stated "[t]he effect of mutations on gene expression suggested the importance of both TATATATA as well as flanking sequences (i.e. the TCAC and G) located, respectively, before and after it, in determining the level of in vivo transcription." In other words, 11 out of the 13 nucleotides have been shown to be important for gene expression, so it is unclear how a sequence with only 75% identity will activate transcription.

Art Unit: 1636

Allowable Subject Matter

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER